SENATE BILL REPORT 5ESSB 5857

As Amended by House, March 4, 2016

Title: An act relating to registration and regulation of pharmacy benefit managers.

Brief Description: Addressing registration and regulation of pharmacy benefit managers.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Parlette, Conway, Becker and Pearson).

Brief History:

Committee Activity: Health Care: 2/12/15, 2/19/15 [DP-WM].

Ways & Means: 2/27/15 [DPS, w/oRec].

Passed Senate: 3/11/15, 49-0.

Second Special Session: Passed Senate: 6/25/15, 44-0.

Passed Senate: 6/30/15, 44-0; 2/17/16, 33-16.

Passed House: 3/04/16, 94-3.

SENATE COMMITTEE ON HEALTH CARE

Majority Report: Do pass and be referred to Committee on Ways & Means.

Signed by Senators Becker, Chair; Dammeier, Vice Chair; Cleveland, Ranking Minority Member; Angel, Bailey, Brown, Conway, Jayapal, Keiser, Parlette and Rivers.

Staff: Mich'l Needham (786-7442)

SENATE COMMITTEE ON WAYS & MEANS

Majority Report: That Substitute Senate Bill No. 5857 be substituted therefor, and the substitute bill do pass.

Signed by Senators Hill, Chair; Braun, Vice Chair; Honeyford, Vice Chair, Capital Budget Chair; Hargrove, Ranking Member; Keiser, Assistant Ranking Member on the Capital Budget; Ranker, Ranking Minority Member, Operating; Bailey, Becker, Billig, Brown, Conway, Fraser, Hewitt, O'Ban, Parlette, Rolfes, Warnick, Hatfield and Kohl-Welles.

Minority Report: That it be referred without recommendation.

Signed by Senators Dammeier, Vice Chair; Hasegawa, Padden and Schoesler.

Staff: Sandy Stith (786-7710)

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This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Background: The 2014 Legislature passed ESSB 6137 requiring pharmacy benefit managers (PBMs) to register with the Department of Revenue to conduct business in this state. PBMs process claims for prescription drugs or medical supplies, provide retail network management for pharmacies, pay pharmacies for prescription drugs or medical supplies, and negotiate rebates with manufacturers for drugs.

Standards are established for auditing pharmacy claims, and for PBMs to use when developing lists of drugs with associated maximum allowable costs, including standards related to the availability of drugs, distribution of the lists, and updates to the list every seven business days. PBMs must establish an appeals process to allow pharmacies to appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the pharmacy paid to the supplier of the drug.

The 2014 legislation did not provide regulatory authority.

Summary of Fifth Engrossed Substitute Bill: PBM registration is moved from the Department of Revenue to the Office of the Insurance Commissioner (OIC). The PBM must pay registration and renewal fees that are established in rule by OIC. These fees must be set at a level which allows the registration, renewal, and oversight activities to be self-supporting.

The Commissioner has enforcement authority over the PBMs and the statutory provisions created in 2014. Any entity that violates the chapter is subject to a civil penalty of \$1,000 for each violation. If the violation was knowing and willful, the civil penalty is \$5,000 for each violation. The Commissioner may write rules to implement RCW 19.340 and to establish registration and renewal fees.

References to the maximum allowable cost (MAC) list are modified to the list of predetermined reimbursement costs for multisource generic drug reimbursement. The PBM must utilize the most up-to-date pricing data to calculate reimbursement to pharmacies for multisource generic drug prices and they must be updated within one business day of any price update or modification. All drugs on the list must be readily available for purchase by network pharmacies from national or regional wholesalers that serve pharmacies in Washington.

A pharmacy, or their contracting agent such as a pharmacy services administrative organization, may appeal its reimbursement for a drug to the PBM for a multisource generic drug if the reimbursement is less than the amount the pharmacy paid to the supplier of the drug. Upon receipt of an appeal, the PBM must supply the pharmacy the national drug code for a product available to the pharmacy from a wholesaler operating in Washington at a price that is less than or equal to the reimbursed amount. An appeal must be complete within 10 business days.

If the pharmacy appeal to the PBM is denied, the PBM must provide the reason for the denial and the national drug code of an equivalent multisource generic drug that has been purchased by another network pharmacy located in Washington at the price listed on the PBM's list price, and the name of a wholesaler operating in Washington where the drug can be purchased by the network pharmacy.

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If the appeal to the PBM is denied or the pharmacy is unsatisfied with the outcome of the appeal, the pharmacy may dispute the denial and request a second level review by the Commissioner, beginning January 1, 2017. All relevant information from the parties may be presented to the Commissioner, and the Commissioner may enter an order directing the PBM to make an adjustment to the disputed claim, deny the pharmacy appeal, or take other actions deemed fair and equitable. The appeal to the Commissioner must be completed within 30 calendar days, and a copy of the decision must be provided to both parties within seven days. The OIC appeals are subject to the Administrative Procedures Act and the Commissioner may authorize the Office of Administrative Hearings to conduct the appeals.

Transparency requirements are added. The PBM must disclose to each plan sponsor providing prescription drug coverage a written explanation of the methodology and sources utilized by the PBM to determine multisource generic drug prices. Multisource generic drug prices must be updated and provided in writing to every plan sponsor within 7 business days whenever there is a pricing change under the contract. The PBM must disclose any differences between the multisource generic drug pricing of drugs dispensed with network retail pharmacies, mail order pharmacies, and other nonretail pharmacies.

The OIC must review the potential to use the independent review organizations that currently review consumer disputes with health plans, as an alternative to the appeal process, and submit recommendations to the Legislature by December 1, 2016.

The chapter establishing the pharmacy benefit manager requirements is created as a new chapter in Title 48 RCW.

Appropriation: None.

Fiscal Note: Available.

Committee/Commission/Task Force Created: No.

Effective Date: Section 1 takes effect on January 1, 2017.

Staff Summary of Public Testimony on Original Bill (Health Care): PRO: We passed a bill last year and it hasn't solved the problems. I hope both sides can sit down and work together. We are very happy with the audit standards that were put in place last year but we are still struggling with the maximum allowable costs list and reimbursement for the cost of the drugs. The reimbursements are below our costs while the big companies reap hundreds of billions in profits. Despite the law, we continue to be paid below costs for the product and we cannot sustain the business this way. The pharmacy benefit managers (PBMs) are not following the law with the appeals process or listing of market prices. They continue to deny requests for reimbursement of the cost of the drugs. The PBMs are not updating the costs of the drugs to reflect the market prices we must pay. They are making special arrangements with big chain stores to serve as their preferred stores; they reimburse the chains twice as much as they pay the small retail pharmacies for the same product. Customers of the local pharmacies appreciate the extra services they have where someone treats us as a person, where the pharmacist knows us and delivers our medications if needed, and allows payments

over time for high-cost medications. We appreciate our local pharmacy and want to ensure they stay in business. We rely on the services they provide.

CON: We negotiated last year's bill and it has only been in effect since mid-June. The proponents did not call and discuss their concerns. The regulatory oversight is not appropriate with the the Office of the Insurance Commissioner. They do not have the appropriate experts in drug pricing. They are funded by insurers and they would not appreciate paying to regulate the PBM issues. We are concerned this could have an adverse impact on the cost of prescription drug benefits. Any limitation on the carriers' ability to manage care is ill advised. We negotiated last year's bill for several years and we would love to sit and talk through what is not working. It is premature to make a change until we know more about how it is working.

Persons Testifying (Health Care): PRO: Senator Parlette, prime sponsor; Kirk Heinz, Kirks Pharmacy; Kari Vanderhowen, Duvall Family Drugs; Bridgett Edgar, PharmaSave Pharmacy; Don Zimmerman, Ian Warren, Costless Pharmacy; David Arnold, Cavallinies Pharmacy; Carolyn Logue, WA Food Industry Assn.; Mary Mclamore, Doris Mandville, Wanda Fredericks, Ebba Jacobson, Maxine Parker, Johnny Miller, Hugh McMillan; Mary Workman, Berrick Bushnell, Ken Baines, citizens.

CON: Mel Sorensen, America's Health Insurance Plans, Express Scripts; Sydney Zvara, Assn. of WA Healthcare Plans; Carrie Tellefson, CVS Health, Regence Blue Shield.

Persons Signed in to Testify But Not Testifying (Health Care): No one.

Staff Summary of Public Testimony on First Substitute (Ways & Means): PRO: We are excited that PBMs won't be allowed to reimburse below costs. We belong to an association that allows us to purchase at the best available price. As mentioned in previous hearings, drug pricing is like a commodity. We ran a report for the one of our three pharmacies and we are now at \$32,000 below our actual costs. We have to borrow money to pay our bills and payroll. We have to resubmit our claims multiple times with no updating by the PBMs of the actual prices. We are averaging ten underpaid claims per day for an average of \$10,000 per month because the PBMs are not updating the acquisition cost lists. We cannot continue to operate with this practice. We will have to close our doors. Since the last time we met with the Committee on Health Care, we have taken another \$6,300 loss. This loss occurred over two weeks. Passing this bill is crucial for the survival of pharmacies. Drugs fluctuate in cost on a daily basis like commodities. PBMs don't adjust for this. We have a lot of stores with pharmacies. We don't know how long we'll be able to continue one-stop shopping. This is a classic example of a bill without a proper enforcement mechanism.

CON: We are opposed to this bill because of Section 2(3) and because this provides massive cost increases for local and state governments. This bill eliminates maximum allowable cost (MAC) pricing. It doesn't take Public Employees Benefit Board, Medicaid, or Labor and Industries into account. This bill needs more discussion. The fiscal note that was published this afternoon begins to show this problem. We represent workers all across the state. Every segment of our membership would be adversely impacted by Section 2(3) of this bill. Please look at this section. We are concerned that our members would see large cost increases. We believe that the increases in generic costs would be great. We have implemented many

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wellness, cost-saving and generics programs. Our retired employees would be adversely affected in having to choose what to pay for. We express real concern about the adverse cost impact of this bill especially those put forth by the Health Care Authority. Most bills have you get more for your money. This has you pay more for what you're currently getting. This is an entirely new regulatory scheme for the OIC. This is regulating disputes of drug pricing. This will have to be paid for by other types of carriers. This would be paid for by policyholders of other types of insurance that is unrelated to policyholders who already pay premium tax.

Persons Testifying (Ways & Means): PRO: Kirk Heinz, Ian Warren, Tim Larsen, Kirks Pharmacy; Carolyn Logue, WA Food Industry Assn.

CON: Carrie Tellefson, CVS Health, Regence Blue Shield; Brenda Wiest, Teamsters 117; Jean Leonard, WA Insurers, NAMIC; Mel Sorensen, America's Health Insurance Plans, Express Scripts.

Persons Signed in to Testify But Not Testifying (Ways & Means): No one.

House Amendment(s):

- Maintains transfer to the OIC and establishes some regulatory oversight of the PBMs.
- Uses the new definitions added in the Senate (list of predetermined reimbursement costs vs. MAC list; and multisource generic drug).
- Modifies the appeal section (all references to pharmacy price guarantees were removed):
 - Pharmacies may bring an appeal to the PBM if their reimbursement is less than the net amount they paid for the drug and the appeal must be complete in 30 days instead of 10;
 - Requires the PBM to uphold an appeal of a pharmacy with fewer than 15 retail outlets in Washington if it can demonstrate it is unable to purchase a therapeutically equivalent product from a supplier in Washington at the PBM's list price;
 - If successful with the appeal, the PBM must make a reasonable adjustment;
 - If unsuccessful, a pharmacy with fewer than 15 retail outlets in Washington may have a second level review with the OIC. Pharmacies with more than 15 retail outlets may provide information to the OIC on their appeals for collection and analysis;
 - The OIC may authorize the appeals be conducted by the Office of Administrative Hearings.
- The OIC with DOH must review the potential to use the IROs for the appeal process, and report to the Legislature by 12/1/16.
- The OIC must conduct a study of the pharmacy chain of supply, with delivery to the Legislature by 11/1/16.
- The PBM must provide information on appeals for retail pharmacies with more than 15 retail outlets for the study.

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